

Opening Statement of Chairman Michael C. Burgess, M.D.
Subcommittee on Health
Hearing on “Examining Medical Product Manufacturer
Communication”
July 12, 2017

(As prepared for delivery)

From last year’s 21st Century Cures Act, to this year’s FDA Reauthorization, this Subcommittee has been steadfast in its commitment to bring federal regulation into the modern era of medicine. Today we will continue that work by examining legislation to update the regulatory framework affecting dissemination of truthful and non-misleading information about FDA-approved products.

I practiced as a physician for several decades, and so I know firsthand how challenging it can be for providers to stay abreast of cutting-edge information in medicine and science. Following FDA-approval of a product, the use of that product rapidly evolves based on patient and provider experience. Frequently the standard of care for a condition is outside of the FDA-approved labeling. Ensuring that healthcare providers are able to access new information generated by real-world evidence is critical to optimizing patient care and outcomes. Particularly in medicine, the old adage holds true—knowledge is power.

Unfortunately, our legal framework for the regulation of manufacturer communication prevents healthcare professionals from receiving the most current scientific information available about the benefits and risks of FDA-approved medicines. A lack of relevant information can lead to physicians making patient care decisions with incomplete information. This is both unfair to the physician and unsafe for the patient.

We owe it to the patient and medical communities to ensure that there is free and full dissemination of truthful and non-misleading scientific and medical information to healthcare professionals.

I would like to yield the balance of my time to Vice Chairman Guthrie and Representative Griffith to discuss their bills—each of which is a targeted approach to addressing the problems presented by our outdated regulatory framework for medical product communication.